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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,529	10/08/2003	Igor Gonda	AERX-055CON6	9730

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/682,529	GONDA ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29,32 and 33* is/are rejected.

7)☒ Claim(s) *31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laube et al. ('094) in view of Burns et al. ('133) and Bechgaard et al.('608).

As to claim 21, Laube et al. disclose a method improving reproducibility of insulin delivered by inhalation, comprising: measuring a patient's glucose level (col.7, lines 36-40); aerosolizing a formulation comprising insulin (col.6, lines 44-47+); inhaling the aerosolized formulation into the lungs of the patient in a manner which allows aerosolized particles of the insulin to deposit on the lung tissue (col.6, lines 22-28), and repeating the measuring, aerosolizing, inhaling in a manner so as to maintain the patient's glucose level in a desired range (col.6, line 45).

The difference between Laube et al. and claim 1 is a formulation comprising monomeric insulin.

Burns et al., in a method of improving reproducibility of insulin delivered by inhalation, also teach the delivery of synthetic analogs of hormones (col.6, line 13).

Bechgaard et al., in a method for maintaining a diabetic's blood glucose within a desired range (col.8, lines 55-60) teach the administration of monomeric insulin to a patient's nasal cavities (col.16, lines 31-38).

It would have been obvious to modify the type of insulin being delivered by Laube et al. to employ synthetic analogs of insulin including monomeric insulin as taught by Burns et al. and Bechgaard et al. as mere substitution of one well known type of insulin for another and because synthetic hormones are more cost effective and less affected by adverse ambient conditions such as heat and cold.

As to claim 22, Bechgaard et al. teach monomeric insulin but do not expressly disclose a particular monomeri insulin. Inasmuch as Bechgaard et al. expressly disclose the use of any monomeric insulin (col.16, lines 31-38), it would have been obvious to employ any particular monomeric insulin including insulin lispro.

As to claim 23, Laube et al. (Table 2) illustrates each aerosolizing is carried out to create an aerosolized dose containing substantially the same amount of insulin that is administered to the NIDDM subjects (i.e. 0.21, 0.23, 0.21).

As to claim 24, Laube et al. disclose the inhaling is repeated with different inhaled volumes of air (col.5, lines 53-55) as evidenced by the range of flow rates from 30 liters/min to 17 liters/min..

As to claims 25 and 26, sulfonylureas as a class of drugs, are known to exhibit hypoglycemic action. A well known tenet in the administration of drugs to patients is the use of a plurality of drugs which act together to cause a synergistic effect within a patient's body. It would have been obvious to further modify the method of administering a formulation of Laube et al. as modified by Burns et al. and Bechgaard et al. to include additional drugs including a sulfonylurea drug because together they would have acted synergistically within a patient's body to produce the desired result. The particular

sulfonylurea drug used would have depended upon the medical needs and tolerance of a given patient for the particular sulfonylurea.

As to claim 27, Bechgaard et al. teach monomeric insulin but do not expressly disclose a particular monomeri insulin. Inasmuch as Bechgaard et al. expressly disclose the use of any monomeric insulin (col.16, lines 31-38), it would have been obvious to employ any particular monomeric insulin including insulin lispro.

3. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laube et al. as modified by Burns et al. and Bechgaard et al. as applied to claims 21-27 above, and further in view of Levine ('411).

The difference between Laube et al. as modified by Burns et al. and Bechgaard et al. and claim 28 is the step of heating air surrounding the aerosolized formulation.

Levine teaches heating air surrounding an aerosolized formulation for the purpose of minimizing loss of aerosol moisture content (col.2, lines 8-11 and lines 37-40).

It would have been obvious to further modify Laube et al. to include the step of heating air surrounding the formulation because it would have provided a means for minimizing loss of aerosol moisture content as taught by Levine.

4. Claims 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laube et al. as modified by Burns et al. and Bechgaard et al. as applied to claims 21-27 above, and further in view of Michaels et al. ('854).

The difference between Laube et al. as modified by Burns et al. and Bechgaard et al. and claim 29 is the aerosolized particles having a diameter in the range of about 1.0 to about 4.0 microns.

Michaels et al. teach the generation of aerosolized particles having a uniform diameter including the range of about 1.0 to about 4.0 microns for the purpose of controlling the sizes of generated aerosolized particles to cause them to deposit in various portions of the respiratory tract including deep into a patient's lung tissue (col.4, lines 16-34).

It would have been obvious to further modify Laube et al. to control the aerosol particle sizes because it would have provided a means for providing aerosol particles having a uniform diameter and for controlling the deposition in various portions of a patient's respiratory tract including deep into a patient's lung tissue as taught by Michaels et al..

As to claim 30, Michaels et al. teach the formulations are aerosolized by being forced through a porous membrane (11) from a disposable container (17).

5. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laube et al. in view of Burns et al. and Bechgaard et al. as applied to claims 21-27 above, and further in view of Hillsman ('158).

The difference between Laube et al. as modified by Burns et al. and Bechgaard et al. and claim 32 is providing a signal when inhaled volume reaches 65% or more of lung capacity of the lungs of the inhaling patient.

Hillsman teaches providing a signal (figs.6-8) of measured inhaled volume of air throughout an inhalation cycle for the purpose of optimizing a patient's breathing patterns to enable the patient to receive a proper dose of aerosolized medicament (col.4, lines 13-16).

It would have been obvious to further modify Laube et al. to provide a signal of measured inhaled volume because it would have provided a means for optimizing a patient's breathing patterns to enable the patient to receive a proper dose of aerosolized medicament as taught by Hillsman.

As to claim 33, Hillsman teaches providing an visual signal of measured inhaled volume of inhaled air over a complete inhalation cycle including when the inhaled volume reaches 80% more of lung capacity of the lungs of the inhaling patient.

Allowable Subject Matter

6. Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
September 21, 2004